

REMARKS/ARGUMENTS

Claims 1, 3-9, 12, 15-19, and 22-25 have been examined. Applicants note with appreciation that these claims are free of any rejections based upon the prior art of record. Claim 3 has been amended as requested by Examiner so that the drawing objection under 37 C.F.R. § 1.83(a) is now moot. Claims 26-36 stand withdrawn as being drawn to a non-elected species. Applicants believe currently pending claim 1 is generic with respect to all pending dependent claims, including withdrawn claims 26-36. As such, re-examination and reconsideration of pending claims 1, 3-9, 12, 15-19, and 22-36 are respectfully requested.

Claims 1, 3-9, 12, 15-19, and 22-25 have been rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The enablement rejection with respect to claims 1, 3-9, 12, 15-19, and 22-25 is traversed as follows.

The test for enablement is whether one reasonably skilled in the art could make the claimed invention from the disclosures in the patent application, when filed, coupled with information known in the art without undue experimentation. M.P.E.P. § 2164.01; *United States v. Teletronics, Inc.*, 857 F.2d 778, 785, 8 U.S.P.Q.2d 1217, 1223 (Fed. Cir. 1988). It is Applicants position that one of ordinary skill in the art at the time the application was filed could have constructed the claimed balloon catheter of claim 1 based on the patent application disclosure without any undue or unreasonable experimentation.

Attached hereto is a Declaration under 37 C.F.R. § 1.132 that has been executed by Udayan Patel who has over fifteen years of product development experience in the medical device field, particularly in designing catheters and balloon catheters. The Declaration states that one of skill in the art at the time the application was filed, May of 2001, could have made the claimed balloon catheter of claim 1 based upon the specification and drawings of the present application ("the '640 application") coupled with information known in the art without undue or unreasonable experimentation. In particular, Mr. Patel states that those of skill in the art in May of 2001 could have constructed the connection between the inflation tube and the balloon in a number of several ways without undue or unreasonable experimentation, particularly in light of the predictability associated with the mechanical arts.

As explained in Mr. Patel's Declaration, independent claim 1 is directed at an intravascular balloon catheter as shown in the alternative constructions of Figs. 5A and 13A of the '640 application. As described on page 10, line 27 through page 13, line 20 and page 14, lines 21-30 of the '640 application, Figs. 5A and 13A show a cross sectional profile of the alternative embodiment at a midpoint of a catheter body at lines 5-5 of Fig. 2 and at lines 13-13 of Fig. 12, respectively. Specifically, as shown in Figs. 2, 4, 5A, and 13A of the '640 application, the intravascular balloon catheter (10) comprises the catheter body (12) and a first balloon structure (14). The catheter body (12) has a proximal end (16), a distal end (18), a guidewire lumen (20), and an axially slit passage (24) along at least a portion thereof. The first balloon structure (14) comprises a balloon (40), a passage (41) slidably receivable over the catheter body (12), and an inflation tube (26) removably receivable in the axially slit passage (24). Per Mr. Patel, those of skill in the art in May of 2001 could have constructed the claimed balloon catheter of claim 1 based on this patent application disclosure without any undue or unreasonable experimentation.

Mr. Patel explains in his Declaration that the Examiner's position outlined on page 3 of the Office Action is incorrect. Per Mr. Patel, those of skill in the art would recognize that claim 1 requires that the passage (41) of the balloon structure (14) is slidably receivable over the catheter body (12) and that the inflation tube (26) of the balloon structure (14) is removably receivable in the axially slit passage (24) of the catheter body (12) as clearly described on page 12, lines 3-19 of the '640 application. Further, those of skill in the art would further recognize that Claim 1 clearly does not require that the inner sleeve (38) be removably received within the axial slit (24) of the catheter body (12).

Mr. Patel's Declaration further provides one simple example illustrated in Appendix B, attached to the Declaration. According to Mr. Patel, this example could have been easily constructed by one of skill in the art in May of 2001 based upon the mid-section illustrations of Figs. 5A and 13A from the '640 application of this claimed embodiment without undue or unreasonable experimentation. In this example, the intravascular balloon catheter (10) comprises a catheter body (12) and a first balloon structure (14). The catheter body (12) has a distal end (18), a guidewire lumen (20), and an axially slit passage (24) along at least a portion

thereof. The first balloon structure (14) comprises a balloon (40), an inner sleeve (38) slidably receivable over the catheter body (12), and an inflation tube (26) removably receivable in the axially slit passage (24). A cross sectional view at a midpoint of the balloon catheter (10) taken along lines 13A-13A is illustrated in Fig. 13A in the '640 application. A distal cross sectional view taken along lines A-A is similar to Fig. 13A, but now shows the sleeve (38) of the balloon structure (14) slidably receivable over the catheter body (12) and the inflation tube (26) of the balloon structure (14) removably receivable in the axially slit passage (24) of the catheter body (12) as clearly described on page 12, lines 3-19 of the '640 application.

In this example, the next distal cross sectional view taken along lines B-B illustrates that a distal end of the inflation tube (26) forms an S shape tube that has a smaller diameter than a width of the narrow portion of the slit (24) so as to extend out of the axial slit (24) and so as to connect to and communicate with the balloon structure (40) as described on page 12, lines 20-23. Mr. Patel disagrees with the Examiner's position that "it is not clear from the original disclosure that the tube 26 would be sufficiently flexible to make an abrupt bend out of slit 24 and make another bend to connect to the balloon 40." Office Action, page 4. Per Mr. Patel, one of skill in the art in the medical device field would recognize that the S shaped inflation tube (26) having a smaller diameter than a width of the narrow portion of the slit (24) may be formed from a variety of flexible and non-flexible materials. From Mr. Patel's fifteen years of experience in researching and developing catheters and balloon catheters, a variety of conventional tubing materials may be employed to form a S shaped tube, such as polymers or metals. In this example, the balloon (40) at a proximal end is attached to the inflation tube (26) and the inner sleeve (38) as shown in view B-B and at a distal end to the inner sleeve (38) as shown in view C-C so as to allow the balloon to be pressurized.

Applicants finally conclude that the Examiner's argument that "no such arrangement is disclosed" on page 4 of the Office Action is moot as the requirements for enablement have been fulfilled per the attached Declaration by Mr. Patel. As a *prima facie* case of lack of enablement has not been established by the Examiner, Applicants respectfully request the removal of this 35 U.S.C. § 112, first paragraph rejection, and allowance of independent claim 1 (and dependent claims 3-9, 12, 15-19, and 22-36).

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Amdt. dated May 27, 2005
Reply to Office Action of October 5, 2004


PATENT

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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